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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,480	04/22/2005	Robert F. Garry	12920.0014.PCUS00	8283
23369 7590 05/18/2007 HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-7195			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/532,480

**Applicant(s)**

GARRY ET AL.

**Examiner**

Stacy B. Chen

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's preliminary amendment filed April 22, 2005 is acknowledged and entered. Claims 1-30 are pending and subject to the following restriction requirement.

#### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group 1, claim(s) 1-8, the special technical feature is a composition comprising SEQ ID NO: 1.
- Group 2, claim(s) 1-8, the special technical feature is a composition comprising SEQ ID NO: 2.
- Group 3, claim(s) 1-8, the special technical feature is a composition comprising SEQ ID NO: 3.
- Group 4, claim(s) 1-8, the special technical feature is a composition comprising SEQ ID NO: 4.
- Group 5, claim(s) 1, 2 and 9-14, the special technical feature is a composition comprising SEQ ID NO: 5.
- Group 6, claim(s) 1, 2 and 9-14, the special technical feature is a composition comprising SEQ ID NO: 13.
- Group 7, claim(s) 1, 2 and 9-14, the special technical feature is a composition comprising SEQ ID NO: 21.
- Group 8, claim(s) 1, 2 and 9-14, the special technical feature is a composition comprising SEQ ID NO: 29.

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- Group 9, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 6.
- Group 10, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 7.
- Group 11, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 8.
- Group 12, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 9.
- Group 13, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 14.
- Group 14, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 15.
- Group 15, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 16.
- Group 16, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 17.
- Group 17, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 22.
- Group 18, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 23.
- Group 19, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 24.
- Group 20, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 25.
- Group 21, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 30.
- Group 22, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 31.

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- Group 23, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 32.
- Group 24, claim(s) 1, 2 and 15-20, the special technical feature is a composition comprising SEQ ID NO: 33.
- Group 25, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 10.
- Group 26, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 11.
- Group 27, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 12.
- Group 28, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 18.
- Group 29, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 19.
- Group 30, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 20.
- Group 31, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 26.
- Group 32, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 27.
- Group 33, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 28.
- Group 34, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 34.
- Group 35, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 35.
- Group 36, claim(s) 1, 2 and 21-26, the special technical feature is a composition comprising SEQ ID NO: 36.

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- Groups 37-72, claim(s) 27 and 28, the special technical feature is a method of treating or preventing a Flavivirus infection comprising administering a composition comprising one of SEQ ID NO: 1-36, respectively.
- Groups 73-108, claim(s) 29 and 30, the special technical feature is an antibody that binds a peptide comprising SEQ ID NO: 1-36, respectively.

3. The inventions listed as Groups 1-108 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature for each of Groups 1-108 is the sequence, SEQ ID NO: 1-36. Each sequence has different amino acid content, and it appears that not one of SEQ ID NO: 1-36 is completely embedded in another sequence of SEQ ID NO: 1-36.

The special technical feature for Group 1 is a composition comprising a peptide having SEQ ID NO: 1, a peptide homologous to SEQ ID NO: 1, or a peptide that is functionally equivalent to SEQ ID NO: 1. According to the specification, SEQ ID NO: 1 mimics HCV E1 protein and inhibits fusion of Flavivirus, specifically HCV, to host cells. Bukh *et al.* (U.S. Patent 5,514,539) discloses HCV E1 peptides, E1 peptide derivatives, and pharmaceutical compositions thereof (abstract and cols 3-4). The peptides described by Bukh *et al.* are expected to be functional equivalents to SEQ ID NO: 1 since they mimic the structure of HCV E1. Therefore, the special technical feature of Group 1 is anticipated by the prior art and the claims lack unity of invention.

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4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**



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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen* 5/14/07  
STACY B. CHEN  
PRIMARY EXAMINER